

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION**

BETH MORRIS,

Plaintiff,

vs.

MEDTRONIC, INC.,

Defendant.

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Case No. 4:22-cv-643-MTS

MEMORANDUM AND ORDER

Before the Court is Defendant Medtronic, Inc.’s Motion to Dismiss, Doc. [21], Counts II–IV of Plaintiff’s First Amended Complaint, Doc. [18], pursuant to Federal Rule of Civil Procedure 12(b)(6). For the reasons that follow, the Court will grant in part and deny in part Defendant’s Motion.

I. BACKGROUND

This product liability case concerns the death of Plaintiff Beth Morris’s husband, allegedly as a result of a defect in the HeartWare Ventricular Assist Device (“HVAD”), an FDA-approved Class III medical device system, manufactured by Defendant. Plaintiff filed a four-count action against Defendant for claims arising under Missouri law for: strict liability (Count I), negligence (Count II), negligence *per se* (Count III), and breach of implied warranty (Count IV). Doc. [18]. In the instant Motion, Defendant seeks to dismiss Counts II, III, and IV for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6). Doc. [21]. Defendant, however, does not seek full dismissal of those claims, but rather seeks to “narrow the issues” in this case by dismissing the part of those Counts “predicated on any conduct other than manufacturing defect,” because, according to Defendant, those type of claims are “expressly and impliedly preempted by federal

law and must be dismissed.” Doc. [24] at 1–2.

II. LEGAL STANDARD

Under Federal Rule of Civil Procedure 12(b)(6), a party may move to dismiss a claim for “failure to state a claim upon which relief can be granted.” Fed. R. Civ. P. 12(b)(6). For a pleading to state a claim for relief it must contain “a short and plain statement of the claim showing that the pleader is entitled to relief.” Fed. R. Civ. P. 8(a). The complaint must contain facts sufficient to state a claim that is plausible on its face. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A claim has “facial plausibility” when the plaintiff pleads factual content that allows the court to draw the “reasonable inference” that the defendant is liable for the misconduct alleged. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). A pleading that offers “labels and conclusions” or “a formulaic recitation of the elements of a cause of action will not do.” *Twombly*, 550 U.S. at 555. And, merely providing “[t]hreadbare recitals of the elements of a cause of action supported by mere conclusory statements, do[es] not suffice.” *Iqbal*, 556 U.S. at 678. While the Court must assume all factual allegations in the complaint are true when considering a Rule 12(b)(6) motion, *Neitzke v. Williams*, 490 U.S. 319, 326–27 (1989) & *Martin v. Iowa*, 752 F.3d 725, 727 (8th Cir. 2014), the Court “need not accept as true a plaintiff’s conclusory allegations or legal conclusions drawn from the facts.” *Glick v. W. Power Sports, Inc.*, 944 F.3d 714, 717 (8th Cir. 2019).

III. DISCUSSION

A. Negligence

Defendant argues Plaintiff’s negligence claim is preempted “*to the extent* Plaintiff’s negligence claim is *based on any theory other than an alleged manufacturing defect*.” Doc. [23] at 8–12 (emphasis added); *see also id.* at 9 (“The *Riegel* Test Is Satisfied For All Claims *Other Than Manufacturing Defect*”) (emphasis added); *id.* at 10 (“Plaintiff’s Allegations About *Non-*

Manufacturing Negligence Are Insufficient to State a Parallel Claim That Evades Preemption”) (emphasis added). Defendant concedes Plaintiff stated a claim for negligence (manufacturing defect) but asks the Court to opine on *all* theories sufficient to state a negligence claim. It is not the Court’s role on a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) to issue piecemeal dismissals of parts of a claim. *BBL, Inc. v. City of Angola*, 809 F.3d 317, 325 (7th Cir. 2015) (“A motion to dismiss under Rule 12(b)(6) doesn’t permit piecemeal dismissals of parts of claims; the question at this stage is simply whether the complaint includes factual allegations that state a plausible claim for relief.”). Rather, the question at this stage is simply to determine whether the Complaint includes factual allegations that state a plausible claim for relief. *Dingxi Longhai Dairy, Ltd. v. Becwood Tech. Grp. LLC*, 635 F.3d 1106, 1109 (8th Cir. 2011) (explaining under Rule 12(b)(6), “a court may dismiss a complaint only if it is clear that *no* relief could be granted under *any* set of facts that could be proved consistent with the allegations” (quoting *Swierkiewicz v. Sorema N.A.*, 534 U.S. 506, 514 (2002))); *cf. Topchian v. JPMorgan Chase Bank, N.A.*, 760 F.3d 843, 849 (8th Cir. 2014) (“[I]t is the facts alleged in a complaint, and not the legal theories, that state a claim.”). Because Plaintiff stated a plausible claim for relief for negligence, notably, as conceded by Defendant, the Court denies Defendant’s Motion to Dismiss Count II.

B. Negligence Per Se

Plaintiff brings a negligence *per se* claim (Count III) based on violations of federal law and a Missouri statute. Doc. [18] ¶¶ 85–91. Defendant argues the claim based on federal law is impliedly preempted under 21 U.S.C. § 337(a) of the Medical Device Amendments (“MDA”) to the Federal Food, Drug and Cosmetic Act (“FDCA”), as interpreted in *Buckman Co. v. Plaintiffs’ Legal Committee*, 531 U.S. 341 (2001).

A state law claim is “impliedly preempted” when it “exist[s] solely by virtue” of a federal requirement. *Buckman*, 531 U.S. at 353. While Plaintiff pled the HVAD is “adulterated” and that such adulteration violates *both* federal law and a Missouri law, Defendant has not shown Mo. Rev. Stat. § 196.015 exists “solely” by virtue of the FDCA. To the contrary, Missouri law itself defines when a “device shall be deemed to be adulterated,” *see* Mo. Rev. Stat. § 196.095, such as when a device’s “quality falls below [] that which it purports or is represented to possess,” *id.* at § 196.095(6), as alleged by Plaintiff, Doc. [18] ¶ 88(d). “[S]imply because conduct violates the FDCA does not mean a state-law claim based on that same conduct depends on the FDCA’s existence.” *Lefavre v. KV Pharm. Co.*, 636 F.3d 935, 944 (8th Cir. 2011) (quoting *Couick v. Wyeth, Inc.*, 3:09-cv-210-RJC, 2009 WL 4644394, at *5 (W.D.N.C. Dec. 7, 2009)).

Moreover, the Court of Appeals for the Eighth Circuit explained that while a plaintiff *must* sue for conduct that *violates* the FDCA to escape express preemption, a plaintiff’s claim is impliedly preempted under *Buckman* if he sues *because* the conduct violates the FDCA. *In re Medtronic, Inc., Sprint Fidelis Leads Prod. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010). Although Plaintiff’s action sounds in conduct that violates the FDCA, she is not suing because the conduct violates the FDCA, but rather, because the HVAD was “dangerously defective and unsafe” under state tort law. Doc. [18] ¶ 87. Therefore, at this stage in the proceedings, the Court concludes Plaintiff’s negligence claim is not impliedly preempted.

C. **Breach of Implied Warranty**

Plaintiff concedes her claim for breach of implied warranty (Count IV) should be dismissed. Doc. [23] at 7. Thus, the Court grants Defendant’s Motion to Dismiss Count IV.


CONCLUSION

The Court grants Defendant's Motion to Dismiss Count IV and denies Defendant's Motion to Dismiss Counts II and III.

Accordingly,

IT IS HEREBY ORDERED that Defendant's Motion to Dismiss, Doc. [21], is **GRANTED** *in part* and **DENIED** *in part*.

Dated this 7th of March, 2023.

A handwritten signature in black ink, appearing to read 'Matthew T. Schelp', written over a horizontal line.

MATTHEW T. SCHELP
UNITED STATES DISTRICT JUDGE